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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/381,747	09/22/1999	MAR TORMO	UTSC:550---/IPAR	4363

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EXAMINER
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CHONG, KIMBERLY

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/381,747

Applicant(s)

TORMO ET AL.

Examiner

Kimberly Chong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 August 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 and 22-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 22-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Status of Application/Amendment/Claims*

Applicant's response filed 08/19/2005 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 05/17/2005 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 08/19/2005, claims 1-20 and 22-49 are pending in the application.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-20 and 22-38 are provisionally rejected under the judicially created doctrine of double patenting over claims 58-65, 72-76, 79-89, 91 and 92 of copending Application No. 08/726,211. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the copending application are drawn to patentably indistinguishable subject matter

The instant claims are drawn to a composition comprising a P-ethoxy polynucleotide that hybridizes to a Bcl-2-encoding polynucleotide to form a neutrally-charged polynucleotide/lipid association wherein the polynucleotide is between 8-50 bases, the P-ethoxy is complementary to the translation initiation site of Bcl-2 mRNA, the polynucleotide is an oligonucleotide comprising SEQ ID NO.1, or wherein said neutral lipid is a phosphatidycholine, phosphatidylglycerol, phosphatidylethanolamine and further the composition comprises an expression cassette that encodes a P-ethoxy polynucleotide. The subject matter of the instant claims is further drawn to a method of inhibiting a Bcl-2 associated disease in a cancer comprising administering a polynucleotide/lipid association that hybridizes to a Bcl-2 encoding polynucleotide wherein the association comprising an oligonucleotide 8-50 bases, the association is delivered in a volume of 0.50-10.0 ml per dose, the association is delivered in an amount from about 5-30 mg per m<sup>2</sup> and the antisense is from 8-50 bases and is a P-ethoxy polynucleotide.

Claims 58-65, 72-76, 79-89, 91 and 92 of copending Application No. 08/726,211 are drawn to a composition comprising a polynucleotide that hybridizes to a Bcl-2-encoding polynucleotide to form a neutrally-charged polynucleotide/lipid association wherein the polynucleotide is between 8-50 bases, the polynucleotide is complementary to the translation initiation site of Bcl-2 mRNA, the polynucleotide is a P-ethoxy oligonucleotide, the

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polynucleotide is an oligonucleotide comprising SEQ ID NO.1, or wherein said neutral lipid is a phosphatidycholine, phosphatidylglycerol, phosphatidylethanolamine and further the composition comprises an expression cassette that encodes a P-ethoxy polynucleotide.

The method of the instant claims are encompassed in the methods of claims 11-15, 18-20, 22-25, 28-30, 44-46, 58-65, 72-76, 79-89, 91 and 92 of copending Application No. 08/726,211 because disease cells having a t(14;18) translocation are cancer cells as evidence by Korsmeyer et al. (Cancer Biology 1993) who states a t(14;18) translocation constitutes the most common chromosomal translocation in human lymphoid malignancies (see page 328).

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Claims 39-49 are provisionally rejected under the judicially created doctrine of double patenting over claims 11-15, 18-20, 22-25, 28-30 and 44,46 of copending Application No. 08/726,211. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the copending application are drawn to patentably indistinguishable subject matter

The subject matter of the instant claims are drawn to a method of inhibiting a Bcl-2 associated disease in a cell that expresses both Bcl-2 and Bax and comprises administering a polynucleotide/lipid association that hybridizes to a Bcl-2 encoding polynucleotide wherein the association comprising an oligonucleotide 8-50 bases, the association is delivered in a volume of 0.50-10.0 ml per dose, the association is delivered in an amount from about 5-30 mg per m<sup>2</sup> and the antisense is from 8-50 bases.

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The subject matter of the claims 11-15, 18-20, 22-25, 28-30, 44-46 of copending Application No. 08/726,211 are drawn to a method of inhibiting a Bcl-2 associated disease in a cell, wherein the cells have a t(14;18) translocation and wherein the method comprises administering a polynucleotide/lipid association that hybridizes to a Bcl-2 encoding polynucleotide wherein the association comprising an oligonucleotide 8-50 bases, the association is delivered in a volume of 0.50-10.0 ml per dose, the association is delivered in an amount from about 5-30 mg per m<sup>2</sup> and the antisense is from 8-50 bases.

The method of the instant claims are encompassed in the methods of claims 11-15, 18-20, 22-25, 28-30, 44-46 of copending Application No. 08/726,211 because as evidenced by Korsmeyer et al. (Cancer Biology 1993) a cell comprises both Bcl-2 and Bax which are essential in determining the survival or death of cells following an apoptotic stimulus (see Abstract and page 331).

### ***Response to Applicant's Arguments***

### ***Correction of Filing Receipt***

It is noted that Applicants are requesting correcting of filing receipt. The request has been forwarded to the appropriate department.

### ***Claim Rejections - 35 USC § 112***

The rejection of claims 10-20, 25 and 39-49 under 35 U.S.C. 112, first paragraph enablement, in the Office Action mailed 02/01/2001 has been withdrawn in response to Applicant's arguments.

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The rejection of claims 1-9, 21-24 and 26-38 as being obvious under 35 U.S.C. 103(a) over Evan (WO 93/20200) or Reed (WO 95/08350) or Green et al. (U.S. Patent No. 5, 583,034) each in view of Lopez-Berestein et al. (U.S. Patent No. 5, 855,911) has been overcome due to Applicant's statement of common obligation of assignment between Lopez-Berestein et al. (U.S. Patent No. 5, 855,911) and the instant application.

MPEP 706.02(l)(2) II states "...if the applicant(s) or an attorney or agent of record makes a statement to the effect that the application and the reference were, at the time the invention was made, owned by, or subject to an obligation of assignment, the same person.", this statement is sufficient evidence to establish common ownership at the time the invention was made.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

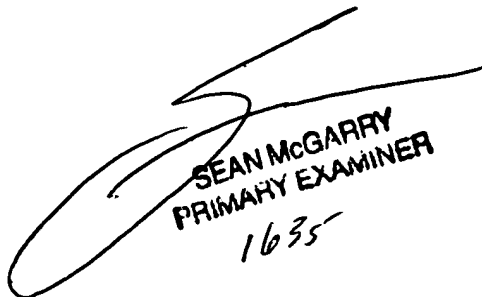
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Kimberly Chong  
Examiner  
Art Unit 1635

  
SEAN MCGARRY  
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